General

Guideline Title

Clinical practice guideline for the diagnosis and management of acute bacterial sinusitis in children aged 1 to 18 years.

Bibliographic Source(s)

Wald ER, Applegate KE, Bordley C, Darrow DH, Glode MP, Marcy SM, Nelson CE, Rosenfeld RM, Shaikh N, Smith MJ, Williams PV, Weinberg ST. Clinical practice guideline for the diagnosis and management of acute bacterial sinusitis in children aged 1 to 18 years. Pediatrics. 2013 Jul;132(1):e262-80. [104 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Clinical practice guideline: management of sinusitis. Pediatrics. 2001 Sep;108(3):798-808. [79 references]

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 12, 2016 – Fluoroquinolone Antibacterial Drugs : The U.S. Food and Drug Administration (FDA) is advising that the serious side effects associated with fluoroquinolone antibacterial drugs generally outweigh the benefits for patients with sinusitis, bronchitis, and uncomplicated urinary tract infections who have other treatment options. For patients with these conditions, fluoroquinolones should be reserved for those who do not have alternative treatment options.

Recommendations

Major Recommendations

Major Recommendations

Definitions for the quality of the evidence (A-D, X) and the strength of the recommendation (strong recommendation, recommendation, option) are provided at the end of the "Major Recommendations" field.

Key Action Statement (KAS) 1

Clinician should make a presumptive diagnosis of acute bacterial sinusitis when a child with an acute upper respiratory tract infection (URI) presents with the following:

- Persistent illness (i.e., nasal discharge [of any quality] or daytime cough or both lasting more than 10 days without improvement)
  OR
- Worsening course (i.e., worsening or new onset of nasal discharge, daytime cough, or fever after initial improvement)
  OR
- Severe onset (i.e., concurrent fever [temperature ≥39°C/102.2°F] and purulent nasal discharge for at least 3 consecutive days) (Evidence Quality: Grade B; Recommendation)

KAS Profile 1

- Aggregate evidence quality: B
- Benefit: Diagnosis allows decisions regarding management to be made. Children likely to benefit from antimicrobial therapy will be identified.
- Harm: Inappropriate diagnosis may lead to unnecessary treatment. A missed diagnosis may lead to persistent infection or complications.
- Cost: Inappropriate diagnosis may lead to unnecessary cost of antibiotics. A missed diagnosis leads to cost of persistent illness (loss of time from school and work) or cost of caring for complications.
- Benefits-harm assessment: Preponderance of benefit
- Value judgments: None
- Role of patient preference: Limited
- Intentional vagueness: None
- Exclusions: Children aged <1 year or older than 18 years and with underlying conditions
- Strength: Recommendation

Key Action Statement 2A

Clinicians should not obtain imaging studies (plain films, contrast-enhanced computed tomography [CT], magnetic resonance imaging [MRI], or ultrasonography) to distinguish acute bacterial sinusitis from viral URI (Evidence Quality: Grade B; Strong Recommendation).

KAS Profile 2A

- Aggregate evidence quality: B; overwhelmingly consistent evidence from observational studies
- Benefit: Avoids exposure to radiation and costs of studies. Avoids unnecessary therapy for false-positive diagnoses.
- Harm: None
- Cost: Avoids cost of imaging
- Benefits-harm assessment: Exclusive benefit
- Value judgments: Concern for unnecessary radiation and costs
- Role of patient preference: Limited. Parents may value a negative study and avoidance of antibiotics as worthy of radiation but panel disagrees.
- Intentional vagueness: None
- Exclusions: Patients with complications of sinusitis
- Strength: Strong recommendation

Key Action Statement 2B

Clinicians should obtain a contrast-enhanced CT scan of the paranasal sinuses and/or an MRI with contrast whenever a child is suspected of having orbital or central nervous system complications of acute bacterial sinusitis (Evidence Quality: Grade B; Strong Recommendation).

KAS Profile 2B

- Aggregate evidence quality: B; overwhelmingly consistent evidence from observational studies
- Benefit: Determine presence of abscesses, which may require surgical intervention; avoid sequelae because of appropriate aggressive

management.
- Harm: Exposure to ionizing radiation for CT scans; need for sedation for MRI
- Cost: Direct cost of studies
- Benefits-harm assessment: Preponderance of benefit
- Value judgments: Concern for significant complication that may be unrecognized and, therefore, not treated appropriately
- Role of patient preference: Limited
- Intentional vagueness: None
- Exclusions: None
- Strength: Strong recommendation

Key Action Statement 3

Initial Management of Acute Bacterial Sinusitis

3A: "Severe onset and worsening course" acute bacterial sinusitis. The clinician should prescribe antibiotic therapy for acute bacterial sinusitis in children with severe onset or worsening course (signs, symptoms, or both) (Evidence Quality: Grade B; Strong Recommendation).

KAS Profile 3A

- Aggregate evidence quality: B; randomized controlled trials with limitations
- Benefit: Increase clinical cures, shorten illness duration, and may prevent suppurative complications in a high-risk patient population.
- Harm: Adverse effects of antibiotics
- Cost: Direct cost of therapy
- Benefits-harm assessment: Preponderance of benefit
- Value judgments: Concern for morbidity and possible complications if untreated
- Role of patient preference: Limited
- Intentional vagueness: None
- Exclusions: None
- Strength: Strong recommendation

3B: "Persistent illness." The clinician should either prescribe antibiotic therapy OR offer additional outpatient observation for 3 days to children with persistent illness (nasal discharge of any quality or cough or both for at least 10 days without evidence of improvement) (Evidence Quality: Grade B; Recommendation).

KAS Profile 3B

- Aggregate evidence quality: B; randomized controlled trials with limitations
- Benefit: Antibiotics increase the chance of improvement or cure at 10 to 14 days (number needed to treat, 3–5); additional observation may avoid the use of antibiotics with attendant cost and adverse effects.
- Harm: Antibiotics have adverse effects (number needed to harm, 3) and may increase bacterial resistance. Observation may prolong illness and delay start of needed antibiotic therapy.
- Cost: Direct cost of antibiotics as well as cost of adverse reactions; indirect costs of delayed recovery when observation is used.
- Benefits-harm assessment: Preponderance of benefit (because both antibiotic therapy and additional observation with rescue antibiotic, if needed, are appropriate management).
- Value judgments: Role for additional brief observation period for selected children with persistent illness sinusitis, similar to what is recommended for acute otitis media, despite the lack of randomized trials specifically comparing additional observation with immediate antibiotic therapy and longer duration of illness before presentation.
- Role of patient preference: Substantial role in shared decision-making that should incorporate illness severity, child's quality of life, and caregiver values and concerns.
- Intentional vagueness: None
- Exclusions: Children who are excluded from randomized clinical trials of acute bacterial sinusitis, as defined in the text
- Strength: Recommendation

Key Action Statement 4

Clinicians should prescribe amoxicillin with or without clavulanate as first-line treatment when a decision has been made to initiate antibiotic treatment of acute bacterial sinusitis (Evidence Quality: Grade B; Recommendation).

KAS Profile 4

- Aggregate evidence quality: B; randomized controlled trials with limitations
- Benefit: Increase clinical cures with narrowest spectrum drug; stepwise increase in broadening spectrum as risk factors for resistance increase
- Harm: Adverse effects of antibiotics including development of hypersensitivity
- Cost: Direct cost of antibiotic therapy
- Benefits-harm assessment: Preponderance of benefit
- Value judgments: Concerns for not encouraging resistance if possible
- Role of patient preference: Potential for shared decision-making that should incorporate the caregiver's experiences and values.
- Intentional vagueness: None
- Exclusions: May include allergy or intolerance
- Strength: Recommendation

Key Action Statement 5A

Clinicians should reassess initial management if there is either a caregiver report of worsening (progression of initial signs/symptoms or appearance of new signs/symptoms) OR failure to improve (lack of reduction in all presenting signs/symptoms) within 72 hours of initial management (Evidence Quality: Grade C; Recommendation).

KAS Profile 5A

- Aggregate evidence quality: C; observational studies
- Benefits: Identification of patients who may have been misdiagnosed, those at risk of complications, and those who require a change in management
- Harm: Delay of up to 72 hours in changing therapy if patient fails to improve
- Cost: Additional provider and caregiver time and resources
- Benefits-harm assessment: Preponderance of benefit
- Value judgments: Use of 72 hours to assess progress may result in excessive classification as treatment failures if premature; emphasis on importance of worsening illness in defining treatment failures.
- Role of patient preferences: Caregivers determine whether the severity of the patient's illness justifies the report to clinician of the patient's worsening or failure to improve.
- Intentional vagueness: None
- Exclusions: Patients with severe illness, poor general health, complicated sinusitis, immune deficiency, previous sinus surgery, or coexisting bacterial illness
- Strength: Recommendation

Key Action Statement 5B

If the diagnosis of acute bacterial sinusitis is confirmed in a child with worsening symptoms or failure to improve in 72 hours, then clinicians may change the antibiotic therapy for the child initially managed with antibiotic OR initiate antibiotic treatment of the child initially managed with observation (Evidence Quality: Grade D; Option based on expert opinion, case reports, and reasoning from first principles).

KAS Profile 5B

- Aggregate evidence quality: D; expert opinion and reasoning from first principles
- Benefit: Prevention of complications, administration of effective therapy
- Harm: Adverse effects of secondary antibiotic therapy
- Cost: Direct cost of medications, often substantial for second-line agents
- Benefits-harm assessment: Preponderance of benefit
- Value judgments: Clinician must determine whether cost and adverse effects associated with change in antibiotic is justified given the severity of illness.
- Role of patient preferences: Limited in patients whose symptoms are severe or worsening but caregivers of mildly affected children who are failing to improve may reasonably defer change in antibiotic.
- Intentional vagueness: None
- Exclusions: None
- Strength: Option

Definitions:

Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

Evidence Quality

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed randomized controlled trials (RCTs) or diagnostic studies on relevant population	Strong recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation/Strong Recommendation	
C. Observational studies (case-control and cohort design)	Recommendation	
D. Expert opinion, case reports, reasoning from first principles	Option	No Recommendation
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Recommendation/Strong Recommendation	

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Acute bacterial sinusitis

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Allergy and Immunology

Family Practice

Infectious Diseases

Otolaryngology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To update the American Academy of Pediatrics clinical practice guideline regarding the diagnosis and management of acute bacterial sinusitis in children and adolescents

Target Population

Children, aged 1 to 18 years, with acute bacterial sinusitis

Note: This guideline does not consider neonates and children younger than 1 year or children with anatomic abnormalities of the sinuses, immunodeficiencies, cystic fibrosis, or primary ciliary dyskinesia.

Interventions and Practices Considered

Diagnosis/Evaluation

1. Physical examination and evaluation of symptoms
2. Contrast-enhanced computed tomography (CT) or magnetic resonance imaging (MRI) when child is suspected of having orbital or central nervous system complications

Management

1. Outpatient observation for 3 days
2. Antibiotic therapy
    - Amoxicillin with or without clavulanate
    - High-dose amoxicillin-clavulanate
    - Clindamycin and cefixime OR linezolid and cefixime OR levofloxacin
3. Reassess initial management if worsening or failure to improve reported

Major Outcomes Considered

- Symptom severity
- Child's quality of life
- Cost of antibiotics
- Ease of administration
- Caregiver concerns about potential adverse effects of antibiotics
- Persistence of respiratory symptoms, or development of complications

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Searches of PubMed were performed by using the same search term as in the 2001 report. All searches were limited to English-language and human studies. Three separate searches were performed to maximize retrieval of the most recent and highest-quality evidence for pediatric sinusitis. The first limited results to all randomized controlled trials (RCTs) from 1966 to 2009, the second to all meta-analyses from 1966 to 2009, and the third to all pediatric studies (limited to ages <18 years) published since the last technical report (1999–2009). Additionally, the Web of Science was queried to identify studies that cited the original American Academy of Pediatrics (AAP) guidelines. This literature search was replicated in July 2010 and November 2012 to capture recently published studies. The complete results of the literature review are published separately in the technical report (see the "Availability of Companion Documents").

17 randomized studies of sinusitis in children were identified and reviewed. Only 3 trials met inclusion criteria. Because of significant heterogeneity among these studies, formal meta-analyses were not pursued.

Number of Source Documents

17 randomized studies of sinusitis in children were identified and reviewed. Only 3 trials met inclusion criteria.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
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B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation/Strong Recommendation	
C. Observational studies (case-control and cohort design)	Recommendation	
D. Expert opinion, case reports, reasoning from first principles	Option	No Recommendation
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Recommendation/Strong Recommendation	

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

The results from the literature review were used to guide development of the key action statements included in this document. These action statements were generated by using BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor, Yale School of Medicine, New Haven, CT), an interactive software tool that leads guideline development through a series of questions that are intended to create a more actionable set of key action statements. BRIDGE-Wiz also incorporates the quality of available evidence into the final determination of the strength of each recommendation.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In June 2009, the American Academy of Pediatrics (AAP) convened a new subcommittee to review and revise the clinical practice guideline published by the AAP in 2001. It was developed by a subcommittee of the Steering Committee on Quality Improvement and Management that included physicians with expertise in the fields of primary care pediatrics, academic general pediatrics, family practice, allergy, epidemiology and informatics, pediatric infectious diseases, pediatric otolaryngology, radiology, and pediatric emergency medicine.

The AAP policy statement "Classifying Recommendations for Clinical Practice Guidelines" was followed in designating levels of recommendations. Definitions of evidence-based statements are provided (see the "Rating Scheme for the Strength of the Recommendations" field).

Rating Scheme for the Strength of the Recommendations

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Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

This guideline was reviewed by multiple groups in the American Academy of Pediatrics (AAP) and 2 external organizations. Comments were compiled and reviewed by the subcommittee, and relevant changes were incorporated into the guideline.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis of acute bacterial sinusitis, appropriate use of imaging procedures, and judicious use of antibiotics

Potential Harms

- Adverse effects of antibiotic therapy, including hypersensitivity, allergic reactions and bacterial resistance
- Observation may prolong illness and delay start of needed antibiotic therapy.
- Exposure to ionizing radiation for computed tomography (CT) scans and the need for sedation for magnetic resonance imaging (MRI)
- Inappropriate diagnosis may lead to unnecessary treatment. A missed diagnosis may lead to persistent infection or complications.

Qualifying Statements

Qualifying Statements

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Wald ER, Applegate KE, Bordley C, Darrow DH, Glode MP, Marcy SM, Nelson CE, Rosenfeld RM, Shaikh N, Smith MJ, Williams PV,

Weinberg ST. Clinical practice guideline for the diagnosis and management of acute bacterial sinusitis in children aged 1 to 18 years. Pediatrics. 2013 Jul;132(1):e262-80. [104 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2001 Sep (revised 2013 Jul)

Guideline Developer(s)

American Academy of Pediatrics - Medical Specialty Society

Source(s) of Funding

The American Academy of Pediatrics (AAP) has neither solicited nor accepted any commercial involvement in the development of the content of this publication. Only money from the AAP was used to fund the development of the guideline.

Guideline Committee

Subcommittee on Management of Sinusitis

Composition of Group That Authored the Guideline

Committee Members: Ellen R. Wald, MD, FAAP; Kimberly E. Applegate, MD, MS, FAAP; Clay Bordley, MD, MPH, FAAP; David H. Darrow, MD, FAAP; Mary P. Glode, MD, FAAP; S. Michael Marcy, MD, FAAP; Nader Shaikh, MD, FAAP; Michael J. Smith, MD, MSCE, FAAP; Paul V. Williams, MD, FAAP; Stuart T. Weinberg, MD, FAAP; Carrie E. Nelson, MD, MS; Richard M. Rosenfeld, MD, MPH, FAAP

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Financial Disclosures/Conflicts of Interest

All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors.

None of the participants had financial conflicts of interest.

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Guideline Availability

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site .

Print copies: Available from the American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

Availability of Companion Documents

The following is available:

- Technical report: evidence for the diagnosis and treatment of acute uncomplicated sinusitis in children: a systematic overview. Pediatrics 2013 June;132(1):E284. Available from the American Academy of Pediatrics (AAP) Policy Web site .

Print copies: Available from the American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on November 16, 2001. The information was verified by the guideline developer as of December 5, 2001. This summary was updated by ECRI Institute on September 13, 2013. This summary was updated by ECRI Institute on May 18, 2016 following the U.S. Food and Drug Administration advisory on Fluoroquinolone Antibacterial Drugs.

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